Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Removal of myomas in asymptomatic patients to improve fertility and/or reduce miscarriage rate: a guideline.

Bibliographic Source(s)

Practice Committee of the American Society for Reproductive Medicine. Removal of myomas in asymptomatic patients to improve fertility and/or reduce miscarriage rate: a guideline. Fertil Steril. 2017 Sep;108(3):416-25. [59 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
NO	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition
UNKNOWN	Multidisciplinary Group
UNKNOWN	Methodologist Involvement

▮▯▯▯▯	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▮▮▮▮▯	Search Strategy
▮▮▮▮▮	Study Selection
▮▮▮▮▮	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▮▯▯	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▮	Evidence Summary Supporting Recommendations
▮▮▮▯▯	Rating the Strength of Recommendations
▮▮▮▮▯	Specific and Unambiguous Articulation of Recommendations
▮▯▯▯▯	External Review
▮▮▮▯▯	Updating

Recommendations

Major Recommendations

Definitions for the level of evidence (Level I-III) and strength of the recommendations (Grade A-C) are given at the end of the "Major Recommendations" field.

What Is the Impact of Leiomyomas on Reproductive Outcome?

Summary Statements

> Heterogeneous study designs, inconsistent nomenclature, continuous nature of leiomyoma size and location, and insufficient patient recruitment significantly limit the interpretation of results from existing studies that evaluate the impact of fibroids on the likelihood of achieving pregnancy and maintenance of pregnancy.
> There is insufficient evidence to conclude that myomas reduce the likelihood of achieving pregnancy with or without fertility treatment. (Grade C)
> There is insufficient evidence to determine that a specific myoma size, number, or location (excluding submucosal myomas or intramural myomas impacting the endometrial cavity contour) is associated with a reduced likelihood of achieving pregnancy or an increased risk of early pregnancy loss. (Grade C)

Does Myomectomy Improve Fertility Outcomes for Women with Intramural or Subserosal Fibroids?

Summary Statements

There is insufficient evidence that removal of subserosal fibroids improves fertility. (Grade C)
There is fair evidence that myomectomy does not impair reproductive outcomes (clinical pregnancy rates, live-birth rates) following assisted reproductive technology (ART). (Grade B)

Does Myomectomy Impact the Likelihood of Pregnancy Loss?

Summary Statement

There is insufficient evidence that myomectomy (laparoscopic or open) reduces miscarriage rates. (Grade C)

Does Resection of Submucosal Fibroids (Type 0, 1, or 2) Improve Fertility?

Summary Statement

There is fair evidence that hysteroscopic myomectomy for submucosal fibroids improves clinical pregnancy rates. (Grade B)

Does Hysteroscopic Resection of Submucosal Myomas Affect Miscarriage Rates?

Summary Statement

There is insufficient evidence to conclude that hysteroscopic myomectomy reduces the likelihood of early pregnancy loss in women with infertility and a submucous fibroid. (Grade C)

Recommendations

In asymptomatic women with cavity-distorting myomas (intramural with a submucosal component or submucosal), myomectomy (open or laparoscopic or hysteroscopic) may be considered to improve pregnancy rates.
Myomectomy is generally not advised to improve pregnancy outcomes in asymptomatic infertile women with non–cavity-distorting myomas. However, myomectomy may be reasonable in some circumstances, including but not limited to severe distortion of the pelvic architecture complicating access to the ovaries for oocyte retrieval.

Definitions

Level of Evidence

Level I

Systematic review of randomized controlled trials (RCTs)
RCTs

Level II

Systematic review of a combination of RCTs, controlled trials without randomization, and cohort studies
Controlled trials without randomization
Cohort studies
Case-control studies

Level III

Descriptive studies, case series, case reports, letters, nonsystematic reviews, opinions based on clinical experience, and reports of expert committees.

Strength of Recommendations

Grade A: There is good evidence to support the recommendations, either for or against.

Grade B: There is fair evidence to support the recommendations, either for or against.

Grade C: There is insufficient evidence to support the recommendations, either for or against.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Uterine myomas (leiomyomata, fibroids)

Guideline Category

Treatment

Clinical Specialty

Internal Medicine

Obstetrics and Gynecology

Surgery

Intended Users

Physicians

Guideline Objective(s)

To evaluate if uterine myomas impact the likelihood of pregnancy and pregnancy loss, and if myomectomy influences pregnancy outcomes in asymptomatic women

Note: Obstetrical outcomes are outside the scope of this document.

Target Population

Women of reproductive age with myomas

Interventions and Practices Considered

Myomectomy (open, laparoscopic, and hysteroscopic)

Major Outcomes Considered

- Time to pregnancy
- Clinical pregnancy rate
- Live-birth rate
- Miscarriage rate

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

This clinical practice guideline was based on a systematic review of the literature performed in the electronic database MEDLINE through PubMed on March 3, 2016. No limit or filter was used for the time period covered or English language, but articles were subsequently culled for English language.

A combination of the following medical subject headings or text words were used: abortion; ART; assisted reproductive techn*; birth; embolization; embolization/therapeutic; embryo transfer; endoscopic; endoscopy; fertility; fertilization in vitro; fibroid; fibroma; fibromyoma; hysteroscopy; intrauterine; intrauterine insemination; intrauterine pathology; intrauterine pathologies; in vitro fertilization; in vitro fertilisation; IUI; IVF; laparoscopic; laparoscopy; laparotomy; leiomyoma; metroplast*; miscarriage; myoma; myomect*; pregnancy; pregnancy outcome; removal; reproductive techniques, assisted; uterine; uterine myomectomy; uterine neoplasms; uterus.

Initially, titles and abstracts of potentially relevant articles were screened and reviewed to develop inclusion/exclusion criteria (see Table 1 in the original guideline document). Only studies that met the inclusion criteria were assessed in the final analysis. Studies were eligible if they met one of the following criteria: primary evidence (clinical trials) that assessed the effectiveness of a procedure correlated with an outcome measure (pregnancy, ovulation, or live-birth rates); meta-analyses; and relevant articles from bibliographies of identified articles.

Four members of an independent task force reviewed the full articles of all citations that potentially matched the predefined selection criteria. Final inclusion or exclusion decisions were made on examination of the articles in full. Disagreements about inclusion among reviewers were discussed and resolved by consensus or arbitration after consultation with an independent reviewer/epidemiologist.

Number of Source Documents

The electronic search and examination of reference lists from primary and review articles yielded 1,785 studies, of which 88 studies were included.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Level of Evidence

Level I

- Systematic review of randomized controlled trials (RCTs)
- RCTs

Level II

Systematic review of a combination of RCTs, controlled trials without randomization, and cohort studies
Controlled trials without randomization
Cohort studies
Case-control studies

Level III

Descriptive studies, case series, case reports, letters, nonsystematic reviews, opinions based on clinical experience, and reports of expert committees.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The level of the evidence was evaluated using the grading system found in the "Rating Scheme for the Strength of the Evidence" field and is assigned for each reference in the bibliography (see the original guideline document).

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The literature was reviewed to answer the following questions:

What is the impact of leiomyomas on reproductive outcome?
Does myomectomy improve fertility outcomes for women with intramural or subserosal fibroids?
Does myomectomy impact the likelihood of pregnancy loss?
Does resection of submucosal fibroids (type 0, 1, or 2) improve fertility?
Does hysteroscopic resection of submucosal myomas affect miscarriage rates?

The strength of the recommendations was evaluated using the grading system found in the "Rating Scheme for the Strength of the Recommendations" field.

Rating Scheme for the Strength of the Recommendations

Strength of Recommendations

Grade A: There is good evidence to support the recommendations, either for or against.

Grade B: There is fair evidence to support the recommendations, either for or against.

Grade C: There is insufficient evidence to support the recommendations, either for or against.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

This document was reviewed by American Society for Reproductive Medicine members and their input was considered in the preparation of the final document.

The Practice Committee and the Board of Directors of the American Society for Reproductive Medicine have approved this report.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each summary statement that supports the recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- There is fair evidence that myomectomy (open or laparoscopic) for cavity-distorting myomas (intramural or intramural with a submucosal component) improves pregnancy rates and reduces the risk of early pregnancy loss.
- There is fair evidence that hysteroscopic myomectomy for cavity-distorting myomas improves clinical pregnancy rates but insufficient evidence regarding the impact of this procedure on the likelihood of live birth or early pregnancy loss.
- There is fair evidence that hysteroscopic myomectomy for submucosal fibroids improves clinical pregnancy rates.

Refer to the original guideline document for details about potential benefits of specific interventions.

Potential Harms

Refer to the original guideline document for details about potential harms of specific interventions.

Qualifying Statements

Qualifying Statements

- This report was developed under the direction of the Practice Committee of the American Society for Reproductive Medicine as a service to its members and other practicing clinicians. Although this document reflects appropriate management of a problem encountered in the practice of reproductive medicine, it is not intended to be the only approved standard of practice or to dictate an exclusive course of treatment. Other plans of management may be appropriate, taking into account the needs

of the individual patient, available resources, and institutional or clinical practice limitations.
- See the "Limitations of the Literature" section in the original guideline document.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Sep

Guideline Developer(s)

American Society for Reproductive Medicine - Nonprofit Organization

Source(s) of Funding

American Society for Reproductive Medicine (ASRM)

Guideline Committee

Practice Committee of the American Society for Reproductive Medicine (ASRM)

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Financial Disclosures/Conflicts of Interest

All Committee members disclosed commercial and financial relationships with manufacturers or distributors of goods or services used to treat patients. Members of the Committee who were found to have conflicts of interest based on the relationships disclosed did not participate in the discussion or development of this document.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the American Society for Reproductive Medicine (ASRM) Web site .

Availability of Companion Documents

Continuing medical education (CME) credit related to this guideline is available from the American Society for Reproductive Medicine (ASRM) Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on November 29, 2017. The information was verified

by the guideline developer on December 21, 2017.

This NEATS assessment was completed by ECRI Institute on October 23, 2017. The information was verified by the guideline developer on December 21, 2017.

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